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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,861	12/09/2003	Amy L. Hammack	RADNT-035C	3531

7590 04/22/2005

Robert D. Buyan
STOUT, UXA, BUYAN & MULLINS, LLP
Suite #310
4 Venture
Irvine, CA 92618

EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,861	HAMMACK ET AL.	
	Examiner	Art Unit	
	Henry M Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *120903*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

Continuation data is required in the first paragraph of the specification including application numbers and status and any resulting patent numbers.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said catheter body" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 38 recites the limitation "the shaft" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 38 is indefinite as the cited intended use of locating the probe upstream is dependent on the insertion methodology and although it does not impact the device structure, it makes the exact structure indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9, 11-37 and 39-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25, 33 and 36-38 of U.S. Patent No. 6,679,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 9-12, 15-17, 19, 26, 30-32 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/01177 to Hascoet et al. Hascoet et al. teach a probe (catheter) having a shaft, an atraumatic tip (Fig. 1, # 551) and a heat exchange region defined by the fluid channels 872 and 874 (Page 14, lines 13-14). A temperature sensor is provided in an integral lumen (Fig. 8, # 892) that is deployable outward from the shaft by either a pull wire (Fig. 8, # 914) or a ramp like sloping member, 916a, to deflect the sensor in the proper direction (Fig. 8, #

916a). It is reasonable to interpret the ramp and probe as having complementary shapes to insure the proper movement of the probe as it is deployed. The sensor is deflected as an operator extends it from the lumen through an opening (aperture) in the side of the shaft. The sensor is disclosed as being deployable to 10 mm and therefore inherently capable of achieving 1.8 to 3.2 mm. Hascoet et al. disclose a fiber optic sensor with the fiber providing temperature information to the proximal end of the probe for control of the flow and/or temperature of the control liquid (Page 5, lines 33-40), strongly implying a closed loop controller for the heat exchange liquid.

Claims 39, 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,383,144 to Mooney et al. Mooney et al. disclose a catheter with a temperature sensor and a method for measuring (monitoring) a temperature, typically, of blood (abstract). Mooney et al. discloses a deployable sensor (Col. 13, line 33), the use of memory metals (Col. 12, line 11) and a self-deployment means (Col. 12, line 14) in a device for measuring the temperature within a vascular structure (Col. 14, line 42). Mooney et al discloses a thermistor in a tubular probe with the sensor wires within the tubular portion (Fig. 1). The method is disclosed as inserting the sensor into a blood vessel and monitoring the temperature via an external device connected by wires to the sensor (Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 6-7, 18 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/01177 to Hascoet et al. in view of U.S. Patent 6,383,144 to Mooney et al. Both are discussed above. Mooney et al. teach memory metals for the probe and a potting material that releases (from constraint) the probe when within a body allowing the probe to take the shape of the memory material. This provides a self, or automatically, deploying probe. Nitinol is a well known material for shaped memory. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory material and potting technique as taught by Mooney et al. in the device of Hascoet et al. to provide alternative means for deploying a temperature probe without operator activity.

Claims 4, 13 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/01177 to Hascoet et al (Hascoet) in view of U.S. Patent 6,019,783 to Philips et al. Hascoet et al. are discussed above, but do not disclose a thermistor as the sensor or positively cite a controller. Philips et al. teach a controller for use with a heat exchange catheter that uses a thermal electric element to heat or cool the catheter (Col 2, lines 11-17). Either the flow of the fluid and/or the temperature of the fluid may be controlled (Col. 7, lines 37-40). Philips et al. teach a temperature sensor placed within a body that may be a thermocouple, thermistor or any other temperature-sensing element that can be mounted on a catheter (Col. 4, lines 44-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the fluid temperature controller with a thermistor temperature sensors as taught by Philips et al. in the invention of Hascoet et al. as the thermistor is a well known temperature sensor and Hascoet et al. specifically suggests the temperature signal be used for control.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/01177 to Hascoet et al. in view of U.S. Patent 6,366,818 to Bolmsjö. Hascoet et al. are discussed above, but do not teach the use of multiple temperature sensors. Bolmsjö discloses a urethral

catheter with multiple temperature sensors (Col. 5, line 61), deployable from the catheter (Col. 6, line 4). Bolmsjö specifically suggests the use with hyperthermia treatments (Col. 2, line 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the multiple temperature sensors as taught by Bolmsjö in the invention of Hascoet et al. to measure temperature gradients within the body.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/01177 to Hascoet et al. in view of U.S. Patent 6,383,144 to Mooney et al. as applied to claim 6 and further in view of U.S. Patent 6,371,979 to Beyar et al. Hascoet et al. and Mooney et al. are discussed above, but do not teach specific shaped memory materials. Such materials are well known in the art and Beyar et al. disclose the functional equivalency of shaped memory materials including superelastic nickel-titanium and shaped memory polymer (Col. 6, lines 53-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to select either a shape memory polymer or shape memory alloy (Nitinol) as taught by Beyar et al. in the invention of Hascoet et al. as modified by Mooney et al. to achieve the pre-bend quality of the temperature probe.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/01177 to Hascoet et al. in view of U.S. Patent 6,019,783 to Philips et al. as applied to claim 13 and further in view of U.S. Patent 6,366,818 to Bolmsjö. Hascoet et al. and Philips et al. are discussed above, but do not teach the use of multiple temperature sensors. Bolmsjö discloses a urethral catheter with multiple temperature sensors (Col. 5, line 61), deployable from the catheter (Col. 6, line 4). Bolmsjö specifically suggests the use with hyperthermia treatments (Col. 2, line 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the multiple temperature sensors as taught by Bolmsjö in the

invention of Hascoet et al. as modified by Philips et al. to measure temperature gradients within the body.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/01177 to Hascoet et al. as applied to claim 12 above, and further in view of U.S. Patent 6,117,065 to Hastings et al. Hascoet et al. is discussed above, but do not disclose an external lumen. Hastings et al teaches a catheter with an external lumen. The claimed use of an external lumen is not given patentable weight as lumens may be used for many purposes and devices. Further, the position of the temperature probe lumen (internal or external, full or partial length of the catheter) is not disclosed as being critical to its function as confirmed by multiple configurations being claimed in the application. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an external lumen as taught by Hastings et al. in the device of Hascoet et al. as lumens are pervasive in the art and are well know to be of various sizes, shapes and locations.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/01177 to Hascoet et al. Hascoet et al. are discussed above, but do not specifically teach the ramp and sensor having compatible mating surfaces, however, for proper operation, such compatibility is obvious. Such surface could be any compatible surface, including a flat surface.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,383,144 to Mooney et al. as applied to claim 39 above and further in view of WO 94/01177 to Hascoet et al. All are discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the temperature probe ramp as taught by Hascoet et al. in the invention of Mooney et al. to move the temperature sensor away from the catheter body.

Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,383,144 to Mooney et al. Mooney et al. are discussed above by do not disclose a specific vein. Modifying body temperatures using catheter heat exchangers in blood vessels is well known in the art and the use of the femoral vein or inferior vena cava is considered obvious.

Claims 45, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,383,144 to Mooney et al. in view of U.S. Patent 6,019,783 to Philips et al. Mooney et al. are discussed above, but do not disclose a heat exchange controller. Philips et al. teach a controller for use with a heat exchange catheter that uses a thermal electric element to heat or cool the catheter (Col 2, lines 11-17). Either the flow of the fluid and/or the temperature of the fluid may be controlled (Col. 7, lines 37-40). Philips et al. teach a temperature sensor placed within a body that may be a thermocouple, thermistor or any other temperature-sensing element that can be mounted on a catheter (Col. 4, lines 44-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the fluid temperature controller with a thermistor temperature sensors as taught by Philips et al. in the invention of Hascoet et al. as the thermistor is a well known temperature sensor and Hascoet et al. specifically suggests the temperature signal be used for control.

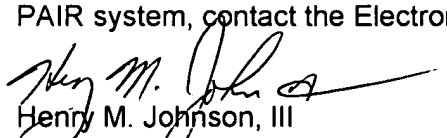
Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,383,144 to Mooney et al. in view of U.S. Patent 6,019,783 to Philips et al. as applied to claim 45 and further in view of WO 94/01177 to Hascoet et al. All are discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the temperature probe ramp as taught by Hascoet et al. in the invention of Mooney et al. as modified by Philips et al. to move the temperature sensor away from the catheter body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Primary Examiner
Art Unit 3739